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**UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA
SAN JOSE DIVISION**

LIFESCAN, INC. and LIFESCAN
SCOTLAND, LTD.,

Plaintiffs,

v.

SHASTA TECHNOLOGIES, LLC,
DECISION DIAGNOSTICS CORP.,
PHARMATECH SOLUTIONS, INC., and
CONDUCTIVE TECHNOLOGIES, INC.,

Defendants.

Case No. V11-04494-EJD

**PLAINTIFFS' MOTION FOR A
PRELIMINARY INJUNCTION**

(FED. R. CIV. P. 65)

Date: March 15, 2013
Time: 9 a.m.
Place: 5th Floor, Courtroom 4
Judge: Hon. Edward J. Davila

NOTICE OF MOTION

PLEASE TAKE NOTICE that Plaintiffs LifeScan, Inc. and LifeScan Scotland, Ltd. (collectively, "LifeScan") hereby move under Fed. R. Civ. P. 65 for a preliminary injunction barring Defendants from contributing to and inducing the infringement of LifeScan's U.S. Patent No. 7,250,105, *e.g.*, selling or offering to sell Defendants' Shasta GenStrip product in the United States.

This motion is based on this Notice; the Memorandum of Points and Authorities; the accompanying Declarations of Dr. Mark Meyerhoff, Peter Menziuso and Eugene M. Gelernter; all pleadings and papers on file in this matter; any oral argument before the Court; and any other matters the Court may request or consider.

Dated: December 14, 2012

/s/ Eugene M. Gelernter

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PRELIMINARY STATEMENT

Plaintiffs LifeScan, Inc. and LifeScan Scotland, Ltd. (collectively "LifeScan") respectfully move under Fed. R. Civ. P. 65 for a preliminary injunction barring Shasta Technologies, LLC, Decision Diagnostics Corp., Pharmatech Solutions, Inc. and Conductive Technologies, Inc. (collectively, "Defendants") from contributing to and inducing the infringement of LifeScan's U.S. Patent No. 7,250,105 by selling or offering to sell their GenStrip product in the United States in violation of 35 U.S.C. § 271 (b) and (c).

LifeScan's OneTouch® Ultra® glucose monitoring systems are the leader in the worldwide market for glucose monitoring systems. LifeScan has built its business by distributing millions of OneTouch meters to diabetics for free or below cost. LifeScan recovers its considerable investments in the business, pays its employees, sponsors ongoing research and development and earns a profit by the sale of disposable test strips for use in the meters. Defendants intend to take advantage of LifeScan's gigantic investment by selling GenStrips for use in certain OneTouch meters at half the price. The launch of the GenStrip – if not enjoined by this Court – will have a devastating effect on LifeScan's business. Declaration of Peter Menziuso ("Menziuso Decl."), ¶¶ 3, 22-25. In the next calendar year alone, Defendants project GenStrip sales of more than \$170 million. *Id.* at Ex. U. The losses to LifeScan will likely be substantially greater. Losses of this magnitude will lead to widespread layoffs, principally here in the Northern District of California where LifeScan is located, and threaten LifeScan's very viability as an ongoing concern. *Id.* ¶ 51.

To protect its investment in its innovative technology, LifeScan has patented its strips and meters, separately and in combination. This lawsuit was brought to enforce those rights. For over a year, even before this litigation began, Defendants have responded to LifeScan's assertion of its patent rights by trying to conceal the structure of their product and the status of their FDA application. As this Court has noted, Defendants refused repeated requests by LifeScan's counsel for samples of the GenStrip and relevant documents before this case was commenced. *See* D.E. 108 at 11. This stonewalling continued after LifeScan filed this case. Instead of complying with Magistrate Judge Grewal's February 2012 Order directing Defendants to produce samples of the

1 GenStrip and the file of their communications with the FDA (D.E. 78 at 2-3), Defendants filed
2 baseless objections, which this Court rejected in July 2012 as "fail[ing] to provide any basis" for
3 challenging the Magistrate's Order (D.E. 107 at 4). Defendants also violated a Stipulation & Order
4 requiring production of documents describing their accused product (D.E. 94) – conduct that resulted
5 in an award of sanctions (D.E. 130) that this Court upheld (D.E. 146).

6 When Defendants finally provided samples of the GenStrip and documents from the
7 FDA file in August and September 2012, LifeScan learned for the first time that the GenStrip has
8 structural features claimed in the '105 patent (in addition to features claimed by the LifeScan patents
9 already in suit), and that the use of the GenStrip with LifeScan's OneTouch® Ultra® meters would
10 infringe the '105 patent. Declaration of Eugene M. Gelernter ("Gelernter Decl."), ¶ 8. LifeScan
11 then moved under Fed. R. Civ. P. 15(a) for leave to file a First Amended Complaint adding the '105
12 patent. As part of their strategy of delay, Defendants Decision Diagnostics Corp. and Pharmatech
13 Solutions, Inc. (collectively, "DDC") opposed that motion with no legitimate basis for doing so –
14 and then abandoned their opposition when the motion was argued on December 5, 2012. *Id.* ¶ 9.

15 Defendants' pattern of concealment continued. At the December 5 hearing, DDC told
16 the Court, in response to a question, that FDA clearance of the GenStrip was "imminent." *Id.* ¶ 10.
17 This was false. Although it was not yet public, the GenStrip had been cleared by the FDA the
18 preceding week, on November 30, 2012. Menziuso Decl., Ex. Q. Knowing that FDA clearance
19 would surely cause LifeScan to seek emergency relief from this Court, DDC apparently elected to
20 conceal the clearance even from its own counsel. *See* Gelernter Decl. ¶ 19. Indeed, on December 5,
21 the day of the hearing Defendants provided an updated production of their communications with the
22 FDA that did *not* include the November 30 clearance letter. As a result, LifeScan only learned of the
23 FDA clearance letter by chance after the hearing, when its counsel saw the FDA clearance letter on
24 Defendant DDC's website. When we advised Defendants that we had seen the clearance letter on
25 DDC's website, it appears DDC responded by blocking access to its website from computers at our
26 offices. *See id.* ¶¶ 11-17.

LifeScan has refrained from filing this motion until now because, until it was clear that the GenStrip would in fact be approved, LifeScan was reluctant to impose on the Court to consider a substantive motion that might prove unnecessary. In the interim, LifeScan has carefully analyzed the GenStrip product and its patent claims, with the goal of narrowing the issues for this motion to those that are most readily capable of expedited resolution. As a result, this motion focuses on only one of the three patents-in-suit, one on which infringement is clear and validity unchallenged.

With the FDA clearance on November 30, GenStrip's launch is now truly imminent. In a conference call with investors on December 11, 2012, DDC representatives stated that they intend to "hit the ground running [with sales of the GenStrip] January 1, 2013." Gelernter Decl., Ex. H at 11:2-4. LifeScan now has no option to protect its patent rights – and to stay alive as a viable business – other than to pursue this motion. The discovery we have received establishes that the intended use of the GenStrip with LifeScan's OneTouch Ultra meters would directly infringe LifeScan's '105 patent and that Defendants would be contributing to and inducing that infringement. The Court should grant a preliminary injunction to preserve the *status quo*.

FACTUAL BACKGROUND

A. LifeScan's OneTouch Ultra System

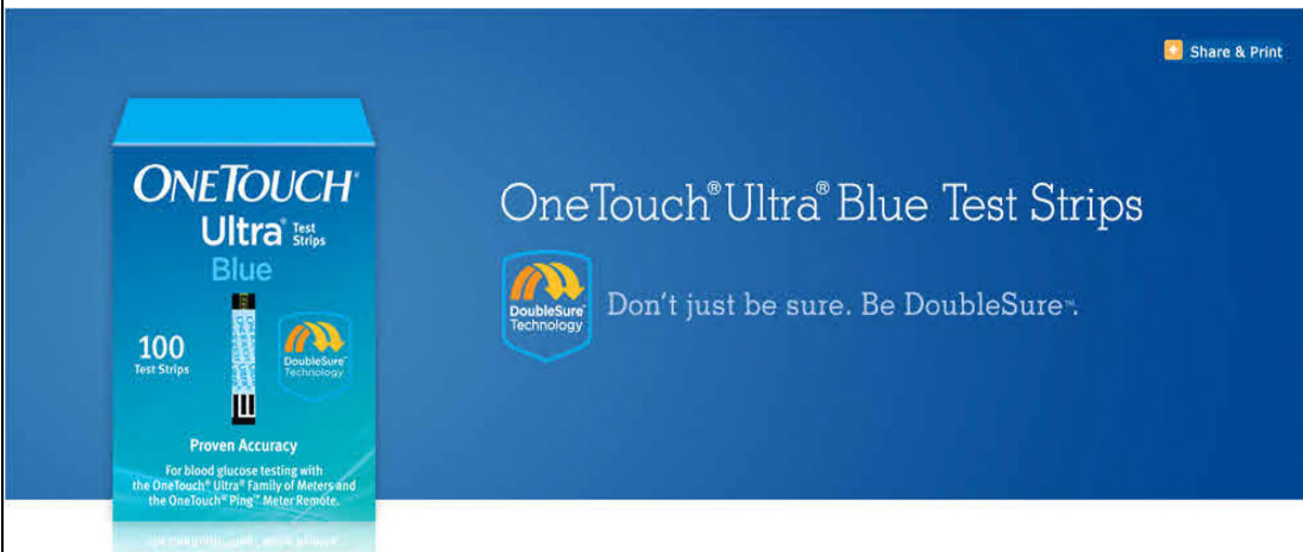
LifeScan's patented glucose monitoring system has two principal components: (1) meters, which LifeScan gives away or sells at less than their cost, and (2) disposable test strips, which LifeScan sells at a profit. *See Menziuso Decl.*, ¶¶ 5, 12-13. Persons with diabetes use the system to monitor their blood glucose levels. Regular testing helps detect hypoglycemia (low blood glucose) or hyperglycemia (high blood glucose), which can lead to life-threatening complications if left untreated. It is one of the most important things that diabetics can do to ensure their health and to prevent long-term complications. This testing typically is done by the individual, at home, several times each day.

LifeScan's OneTouch® Ultra® glucose monitoring systems are the leader in the worldwide market for glucose monitoring systems. To use the OneTouch system, a user places a

disposable test strip in the OneTouch Ultra meter. The user then uses a lancet to draw a small drop of blood and places that drop on the strip. The meter determines the blood glucose level in the sample by measuring the electrical current produced when an electrochemical reaction is triggered in the strip by the presence of glucose. Using the OneTouch system, the diabetic may determine if his or her blood glucose level is within a satisfactory range or if some treatment is required to increase or decrease the blood glucose level. *See id.* ¶ 5.

Several companies in the United States sell blood glucose monitoring systems, each with its own meters and strips. Aside from the Shasta GenStrip, none of the other test strips on the market is capable of working with LifeScan's OneTouch Ultra meters. *Id.* ¶ 7.

An important feature of the OneTouch Ultra system is that it takes two measurements for every blood sample, to protect against errors and to provide enhanced accuracy in blood glucose measurements. LifeScan promotes this feature as its "DoubleSure™ Technology" on its packaging and in its promotional literature. LifeScan's website tells customers that its "DoubleSure™ Technology automatically checks each blood sample twice," Menziuso Decl., Ex. A:



LifeScan's DoubleSure Technology – the subject of the '105 patent – is an important advantage of LifeScan's OneTouch Ultra system over competing systems. *Id.* ¶ 10.

B. The Shasta GenStrip

Ignoring the unprofitable market for LifeScan meters and foregoing the multi-million dollar annual expense associated with manufacturing and distributing meters, Defendants have targeted the LifeScan test strips, where LifeScan earns its profit. Defendant DDC states on its website that the GenStrip is "comparable" to LifeScan's OneTouch Ultra test strips, but "priced significantly (50%) lower." *Id.* Ex. R; *see also id.* (The GenStrip



"will cost about 50% less than the Branded product"). The GenStrip is thus aimed directly at LifeScan's customers. The GenStrip is cleared by the FDA only for use with LifeScan meters. *Id.* Ex. 21. Packaging for the GenStrip on Defendants' websites depicts the GenStrip being used with a LifeScan OneTouch UltraMini meter. *Id.* Exs. S, T (emphasis added). The Shasta GenStrip layout is almost a virtual copy of the LifeScan strip – including its patented DoubleSure Technology.

C. The Impact on LifeScan Absent an Injunction

Introduction of the GenStrip would have a devastating impact on LifeScan. The GenStrip is designed and cleared only for use in LifeScan's meters as a substitute for LifeScan's highly profitable OneTouch Ultra test strips. Moreover, Defendants plan to sell the GenStrip at approximately one-half the price of LifeScan's OneTouch Ultra test strips. As a result, the losses to LifeScan will dwarf the sales that GenStrip makes. LifeScan's lost sales could run to hundreds of millions of dollars. *See* pages 17-18, *infra*. For comparison, LifeScan anticipates \$1 billion total U.S. sales of the OneTouch® Ultra® test strip in 2012. No business can sustain such losses. The result will be widespread layoffs, cutbacks in research and development, reduction of educational efforts; and worse, GenStrip's launch will threaten LifeScan's ongoing viability as a business. A win at trial after several years would be no solace. LifeScan's business will have been irreparably depleted – or ended. And LifeScan would not even recover its money damages, as Defendants do

not have the financial wherewithal to compensate LifeScan for its staggering losses after a trial on the merits. *See infra* at 18-19.

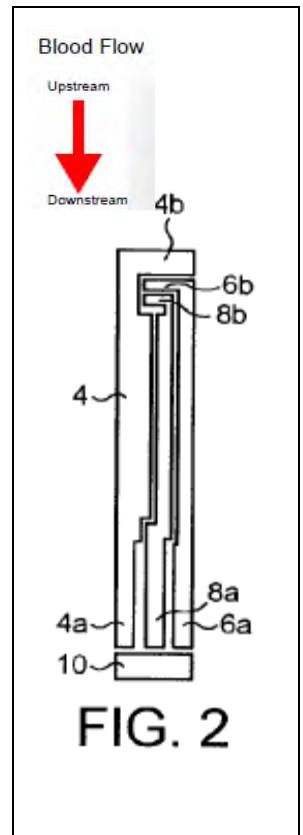
The harm to LifeScan from sale of the GenStrip would be severe and irreparable. These harms could not be compensated in money damages. *See* pages 16-21, *infra*.

D. Use of the Shasta GenStrip Would Infringe the '105 Patent

A copy of LifeScan's '105 patent is attached to the First Amended Complaint (D.E. 170) as Exhibit C. The '105 patent relates to the DoubleSure Technology, a method to improve the reliability and accuracy of glucose measurements. Test strips can give inaccurate results if the test strips' sensors are not fully covered by blood. Ex. C to D.E. 170, at col. 1, lines 39-41. Earlier methods of dealing with this problem did not ensure that the sensors were completely covered by the blood sample, resulting in variable and inaccurate results. *Id.* at col. 1, lines 41-54.

The '105 patent addresses these problems through a innovative test strip design, depicted in Fig. 2 of the patent, shown on the right. A drop of blood is applied to the top of the test strip in Fig. 2 and flows downstream by capillary action. *Id.* at 5:22-25. The test strip has two working sensors (6b and 8b in Fig. 2) that each generates electrical charge carriers proportional to the amount of glucose in the blood. One sensor (8b) is downstream of the other (6b) with respect to blood flow. This allows the current measured at each sensor in response to the application of blood to be compared. *Id.* at 2:10-27.

If the currents measured at each sensor are within a pre-determined range of one another, the sensors are operating properly and both sensors are covered by blood to the same degree. *Id.* at 2:28-39. Because blood flow is restricted so that it must entirely cover the first sensor before covering the second sensor, this ensures that each electrode has been covered completely. *Id.* at 3:43-55. If the difference between the current measured at each sensor is greater than the pre-determined range, the test results will be unreliable (*e.g.*, because of



insufficient blood, user error, manufacturing defect, or some other error) and the test done with that strip should be discarded. Test strips using the design depicted in the '105 patent thus are self-testing for reliability – they are DoubleSure. Claim 3 of the '105 patent describes this technology.

In designing the GenStrip for use with LifeScan's meters, Defendants could have used a different design. *See* Declaration of Mark E. Meyerhoff ("Meyerhoff Decl.") at ¶¶ 43-48. But they chose instead to use the specific design that the '105 patent claims. Use of the GenStrip in conjunction with LifeScan's OneTouch Ultra meters would infringe claim 3 of the '105 patent, and Defendants would violate the patent statute by inducing and contributing to that infringement.

ARGUMENT

THE COURT SHOULD GRANT A PRELIMINARY INJUNCTION

The standard for preliminary injunctive relief in patent cases is governed by Federal Circuit law. *Revision Military, Inc. v. Balboa Mfg. Co.*, No. 2011-1628 2012 U.S. App. LEXIS 24359, *3 (Fed. Cir. Nov. 27, 2012). The standard is well-settled:

To obtain a preliminary injunction, a party must show (1) reasonable likelihood of success on the merits; (2) irreparable harm; (3) that the balance of hardships tips in its favor; and (4) the impact of the injunction on the public interest.

Jack Guttman, Inc. v. Kopykake Enterprises, Inc., 302 F.3d 1352, 1356 (Fed. Cir. 2002). This standard is not "any more or less stringent than those applied to requests for preliminary injunctions in other areas of law." *McData Corp. v. Brocade Communications Sys., Inc.*, 233 F. Supp. 2d 1315, 1319 (D. Colo. 2002) (citing *High Tech. Medical Instrumentation, Inc. v. New Image Indus., Inc.*, 49 F.3d 1551, 1554 (Fed. Cir. 1995)).

All four factors for preliminary injunctive relief are satisfied here.

A. LifeScan Has a Strong Likelihood of Success on the Merits

To demonstrate a "reasonable likelihood of success on the merits" a patentee must show that: (1) it will likely prove infringement; and (2) its infringement claim will likely withstand challenges to the patent's validity and enforceability. *Purdue Pharma L.P. v. Boehringer Ingelheim Gmbh*, 237 F.3d 1359, 1363 (Fed. Cir. 2001). This requires a clear showing that *at least one claim*

1 in one valid patent-at-issue is infringed. *Abbott Labs. v. Andrx Pharms., Inc.*, 473 F.3d 1196, 1213
 2 (Fed. Cir. 2007). An accused infringer cannot defeat a patentee's showing of likelihood of success
 3 on the merits without raising a "substantial question" concerning infringement, validity, or
 4 enforceability. *Abbott Labs. v. Sandoz, Inc.*, 544 F.3d 1341, 1364 (Fed. Cir. 2008).

5 **1. Likelihood of Success for the '105 Patent: Infringement**

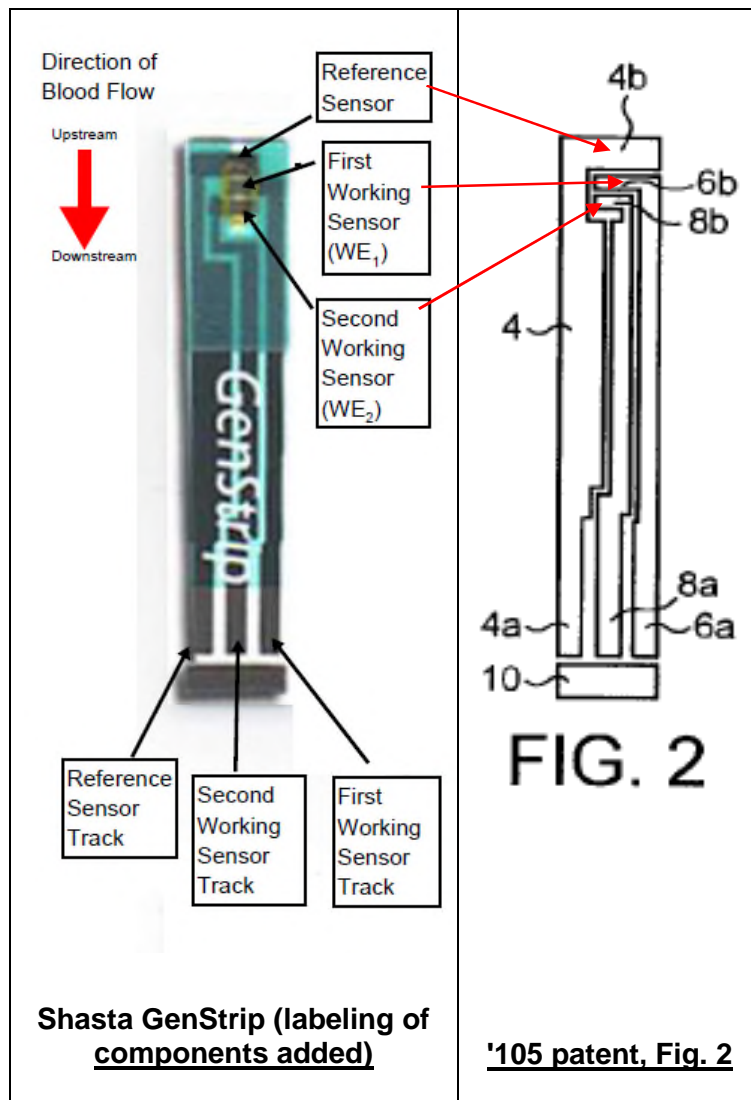
6 Defendants are liable under Section 271(b) and (c) of the patent statute for
 7 contributing to and inducing their customers' direct infringement. This brief first discusses
 8 customers' direct infringement and then discusses Defendants' indirect infringement.

9 **a. Use of the GenStrip Would Directly Infringe the '105 Patent**

10 Generally, an infringement analysis requires two steps. First, the court must construe
 11 the asserted patent claims. Second, the court must compare the properly construed claims to the
 12 accused product or method to determine if the plaintiff is likely to meet its burden of proving
 13 infringement by a preponderance of the evidence. *Pfizer, Inc. v. Teva Pharms. USA, Inc.*, 429 F.3d
 14 1364, 1372-23 (Fed. Cir. 2005). Here, there are no terms that require construction, and there is
 15 infringement under any reasonable claim construction. Use of the GenStrip by Defendants'
 16 customers with LifeScan's OneTouch Ultra meters would directly infringe claim 3 of the '105 patent.

17 Claim 3 of the '105 patent claims a method for measuring the concentration of
 18 glucose in a sample liquid, *e.g.*, blood. That method uses a "measuring device" comprising a test
 19 strip with a particular arrangement of two working sensors and a reference sensor. Each working
 20 sensor generates electric charge carriers proportional to the glucose content of a sample. The two
 21 working sensors are arranged so that one sensor is downstream from the other, *i.e.*, the blood sample
 22 comes in contact with the first sensor before reaching the second sensor. The separate electrical
 23 currents measured at each working sensor are compared by the meter to provide an error indication if
 24 the difference between them exceeds a predetermined threshold. This method of using the test strip
 25 and meter in combination allows the user to confirm that enough blood was applied to cover both
 26 working sensors, which yields a more accurate blood glucose reading.

In designing the GenStrip, Defendants did not need to use the test strip described in claim 3 of the '105 patent. *See* Meyerhoff Decl., ¶¶ 43-48. But they chose to do so. The GenStrip uses the exact arrangement of two working sensors and a reference sensor that the '105 patent claims. Indeed, it is virtually a copy of Fig. 2 of the '105 patent. Blood enters the top of the strip, flows across the reference sensor (4b), which is upstream of the first working sensor (6b) and the second working sensor (8b). It then contacts the first working sensor and then the second working sensor, which is downstream of the first working sensor:



When the GenStrip is inserted in a OneTouch Ultra meter, this arrangement of the reference sensor and the two working sensors allows the system to compare the electric current from

1 each of the working sensors, to determine whether the strip is providing a reliable measurement of
2 glucose in the sample.

3 In his declaration, Dr. Meyerhoff explains in detail how use of the GenStrip with
4 LifeScan's OneTouch Ultra meters meets each limitation of claim 3 of the '105 patent, and directly
5 infringes that claim. *See* Meyerhoff Decl., ¶¶ 27-41, Ex. C. Defendants have no substantial basis for
6 disputing direct infringement.

7 **b. Defendants' Contributory Infringement Under § 271(c)**

8 Section 271(c) applies where a defendant sells or offers to sell in the United States a
9 component or apparatus "that has no use except through practice of the patented method." *Alloc,*
10 *Inc. v. Int'l Trade Comm'n*, 342 F.3d 1361, 1361 (Fed. Cir. 2003). Section 271(c) states:

11 Whoever [1] offers to sell or sells within the United States or imports
12 into the United States [2] a component of a patented machine,
13 manufacture, combination or composition, or a material or apparatus
14 for use in practicing a patented process, constituting a material part of
15 the invention, [3] knowing the same to be especially made or
16 especially adapted for use in an infringement of such patent, and
17 [4] not a staple article or commodity of commerce suitable for
18 substantial noninfringing use, shall be liable as a contributory
19 infringer.

20 Defendants meet all of the requirements for contributory infringement under Section 271(c).

21 First, there is no question that Defendants intend to sell the GenStrip in the U.S.

22 Second, the GenStrip is an "apparatus for use in practicing a patented process" under
23 § 271(c) because its only intended and approved use is with LifeScan's OneTouch meters. As
24 discussed above and in the Meyerhoff Declaration, using the GenStrip with those meters infringes
25 claim 3, and the GenStrip is a "material part of the [claim 3] invention" *Id.*

26 Third, § 271(c)'s knowledge requirement is satisfied because Defendants have been
27 on notice since June 24, 2011 of LifeScan's contention that the use of the GenStrip is likely to
28 infringe the '105 patent. D.E. 108 at 11 (citing D.E. 1 at ¶¶ 34-36). Indeed, Defendants have had
LifeScan's claim charts explaining in detail the basis for its infringement contentions since October
26, 2012. *See* D.E. 152, Ex. B. These facts are more than sufficient to demonstrate the "requisite
knowledge" under § 271(c). *Fujitsu Ltd. v. NetGear, Inc.*, 620 F.3d 1321, 1330 (Fed. Cir. 2010)

(holding that a letter asserting infringement was sufficient to demonstrate knowledge under § 271(c)).¹

Fourth and finally, the GenStrip is specifically made for use with LifeScan's OneTouch Ultra meters, and has no other intended use or purpose. It is not a "staple article of commerce capable of a substantial non-infringing use" under § 271(c). There are no other FDA-approved uses of the Shasta GenStrip, and no substantial non-infringing uses. *See Meyerhoff Decl.* at ¶ 42. Where, as here, the patentee "ma[kes] out a prima facie showing that [the accused infringers'] product was not 'suitable for a substantial non-infringing use,'" the burden shifts to the accused infringer to show that the users actually will use its product "in a non-infringing manner." *Golden Blount, Inc. v. Robert H. Peterson Co.*, 438 F.3d 1354, 1361 (Fed. Cir. 2006). Defendants cannot make that showing because the only use for the GenStrip is in combination with LifeScan's OneTouch Ultra test strips, and that use infringes claim 3 of the '105 patent.

In sum, Defendants are liable under § 271(c) for contributing to their customers' direct infringement of claim 3 of the '105 patent.²

c. Sales of OneTouch Ultra Meters Do Not Exhaust LifeScan's Rights Under the '105 Patent

At the recent hearing on LifeScan's motion for leave to amend the complaint to add the '105 patent, DDC relied on *Quanta Computer, Inc. v. LG Elecs., Inc.*, 553 U.S. 617 (2008), in raising an "exhaustion" argument that DDC had not raised in its motion papers. Where the exhaustion doctrine, sometimes called the "first sale" doctrine, is applicable, it limits a patentee's rights with respect to downstream users of its products. DDC's argument, at core, is that the sale of LifeScan's meter – a component of the patented method – precludes LifeScan from asserting its

¹ *See also Spansion, Inc. v. Int'l Trade Comm'n*, 629 F.3d 1331, 1353 (Fed. Cir. 2010) (the "requisite knowledge for contributory infringement" is "presumed" from the Defendants' knowledge of the patent and the absence of substantial noninfringing uses for their accused product); *Richoh Co. v. Quanta Computer, Inc.*, 550 F.3d 1325, 1338 (Fed. Cir. 2008) (it is appropriate to presume that one who sells a component "*that has no substantial noninfringing use...does so with the intent that the component will be used to infringe.*") (italics in original).

² In addition, Defendants are inducing infringement under Section 271(b) of the patent statute, 35 U.S.C. § 271(b). That section states that "[w]hoever actively induces infringement of a patent shall be liable as an infringer."

1 patent rights with respect to the sale of strips for use in the meter. This contention would relegate
2 LifeScan to the role of giving away its meters or selling them at a loss, while denying it the patent
3 right to sell its compatible test strips at a profit. In fact, *Quanta* mandates the opposite conclusion.
4 It is LifeScan's test strips, not its meters, that "substantially embod[y]" the invention of the '105
5 patent. *Id.* at 633. As a result, LifeScan does not exhaust its patent rights by distributing the meters
6 and instead retains the right to insist on its patent monopoly in the use of its strips to practice the
7 invention claimed in the '105 patent.

8 In *Quanta*, the patentee (LGE) had licensed Intel to make and sell certain
9 microprocessors and chipsets that were components required to practice LGE's patents. Intel sold its
10 chips to Quanta, which combined them with standard parts to form computers. LGE sued Quanta for
11 patent infringement, asserting that the combination of Intel's chips with standard, non-Intel
12 electronics practiced LGE's patents. The Supreme Court found that LGE had exhausted its patent
13 rights by the sale of the Intel chips. This was because "[e]verything inventive about each patent
14 [was] embodied in the Intel Products," and Intel's products "all but completely practice[d] the
15 patent." *Quanta*, 553 U.S. at 633. Intel's chips "substantially embodied" the asserted patents
16 because the chips "had no reasonable noninfringing use and included all the inventive aspects of the
17 patented methods." *Id.* at 638 (emphasis added). "The authorized sale of an article that substantially
18 embodies a patent exhausts the patent holder's rights and prevents the patent holder from invoking
19 patent law to control postsale use of the article." *Id.* at 638 (emphasis added).

20 The *Quanta* Court relied on *United States v. Univis Lens Co.*, 316 U.S. 241 (1942).
21 In *Univis*, the Court held that the sale of bi- and trifocal lens blanks exhausted the patent holder's
22 rights in the finished lenses. "The essential, or inventive, feature of the Univis lens patents was the
23 fusing together of different lens segments to create bi- and trifocal lenses," *Quanta*, 553 U.S. at 632,
24 and the only step needed to practice the patents was grinding and polishing the lens blanks into
25 finished lenses – a standard process in the field. Moreover, in selling the lens blanks, the patent
26 owner had already received in the purchase price "consideration and compensation for both" the lens
27

1 blanks and the right to finish them, and had thus "demanded and received" the "reward" for both "the
2 article and the invention which it embodies."

3 The *Quanta* Court concluded that "*Univis* governs this case." (553 U.S. at 631):

4 As the Court there explained, exhaustion was triggered by the sale of
5 the lens blanks because their only reasonable and intended use was to
6 practice the patent and because they "embodie[d] essential features of
7 [the] patented invention." Each of those attributes is shared by the
8 microprocessors and chipsets Intel sold to Quanta under the License
9 Agreement.

10 "Here, as in *Univis* the incomplete article substantially embodies the patent because the only step
11 necessary to practice the patent is the application of common processes or the addition of standard
12 parts." *Id.* at 633.

13 DDC's theory is that LifeScan's sales of its OneTouch Ultra meters exhaust its patent
14 rights under *Quanta*, leaving LifeScan without the ability to object to the use of GenStrips with
15 LifeScan's meter. But this case is the polar opposite of *Quanta* and *Univis*. First, LifeScan's meters
16 – unlike Intel's microchips and Univis's lens blanks – do not "substantially embody" the invention of
17 claim 3 of the '105 patent. LifeScan's meters do *not* embody "[e]verything inventive" about the '105
18 patent." *Quanta*, 553 U.S. at 633. The meters do *not* "include[] all the inventive aspects of the
19 patented methods." *Id.* at 638 (emphasis added). To the contrary, the *test strips*, not the meters,
20 contain the core inventive features of the '105 patent. Figures 1-7 of the '105 patent depict the test
21 strips or aspects of those strips; none of the figures even illustrates the meters. Similarly, the text of
22 the '105 patent is largely devoted to a description of the test strips. The test strips are anything but
23 standard parts. They embody key aspects of the invention and are usable only with LifeScan's
24 meters. The meters perform relatively simple programming steps of the claimed methods. It is only
25 when the meters are used in combination with novel test strip designed to have the '105 patent's
26 patented configuration that all of the steps of the claimed methods are performed. *See Meyerhoff*
27 Decl. at ¶¶ 43-48.

28 Second, LifeScan's meters – unlike the chips in *Quanta* and the lens blanks in *Univis*
– are capable of a "reasonable noninfringing use." 553 U.S. at 638. The meters are designed to, and
do, measure blood glucose, whether a user takes advantage of the DoubleSure Technology or not.

1 There are a variety of ways that Defendants could have designed test strips to work to measure
 2 glucose with LifeScan's meters that did not use the specific sensor configuration claimed in the '105
 3 patent. *See* Meyerhoff Decl. at ¶¶ 43-48. That is because LifeScan's meters do not substantially
 4 embody the asserted claims of the '105 patent.

5 Third, in contrast to *Univis*, LifeScan does *not* receive its full "reward" for the
 6 patented invention when it sells its OneTouch Ultra meters. *Univis*, 316 U.S. at 251. Rather,
 7 LifeScan does not earn a profit on its OneTouch Ultra meters. LifeScan distributes more than half of
 8 its meters free of charge to physicians and patients, and distributes the rest at sharply reduced prices
 9 below its actual costs. Menziuso Decl., ¶ 39. LifeScan does so with the intent and expectation that
 10 it will receive its full reward for its patented invention over the course of a patient's therapy when the
 11 patient purchases LifeScan's test strips for use with meters that LifeScan distributed without charge
 12 or at nominal cost. *Id.*

13 Under the principles of *Quanta* and *Univis*, LifeScan's sale of meters does not
 14 extinguish its right to profit from the '105 patent.

15 **d. Purchasers of LifeScan's Meters Do Not Have An Implied License to**
 16 **Practice the '105 Patent With the Shasta GenStrip**

17 When DDC opposed LifeScan's motion for leave to amend the complaint to assert the
 18 '105 patent, it offered an incorrect argument that direct infringement does not occur on the theory
 19 that LifeScan's customers have an "implied license" to use LifeScan's OneTouch Ultra meters with
 20 another company's test strips. D.E. 160 at 7. Courts have rejected that argument and it has no merit.

21 An "implied license" defense has prevailed in "relatively few" cases, *Bandag, Inc. v.*
 22 *Al Bolser's Tire Stores, Inc.*, 750 F.2d 903, 925 n.32 (Fed. Cir. 1984), and the burden of establishing
 23 the defense rests with the accused infringer. *Carborundum Co. v. Molten Metal Equip. Innovations*,
 24 72 F.3d 872, 878 (Fed. Cir. 1995). An "implied license" defense cannot prevail unless "the
 25 circumstances of the sale ... *plainly indicate* that the grant of a license should be inferred." *Met-*
 26 *Coil Systems Corp. v. Korner Unlimited, Inc.*, 803 F.2d 684, 686 (Fed. Cir. 1986) (emphasis added).

1 Here, the circumstances of the sale of LifeScan's OneTouch Ultra meters indicates the
 2 exact opposite. LifeScan's OneTouch Ultra monitors are sold in packaging with a notice that
 3 expressly negates any basis for an implied license:

4 Use of the monitoring device included here is protected under one or
 5 more of the following U.S. patents: 7,250,105.... Purchase of this
 6 device does not act to grant a use license under these patents. Such a
 license is granted only when the device is used with OneTouch®
 Ultra® Test strips.

7 Ex. B to Menziuso Decl.

8 In its recent decision granting LifeScan's motion to file an amended complaint adding
 9 the '105 patent, this Court took note of "the above express limitation to the license found on the
 10 packaging for Plaintiffs' product" and concluded that Defendants "have not proven that Plaintiffs'
 11 warning does not preclude the finding of an implied license." D.E. 169 at 6. That decision is
 12 consistent with other cases involving the notice on LifeScan's packaging.

13 In *LifeScan Inc. v. Polymer Tech. Int'l Corp.*, No. C94-672R, 1995 U.S. Dist. LEXIS
 14 4916, *41-45 (W.D. Wash. Jan. 3. 1995), the court relied on LifeScan's packaging notice in rejecting
 15 arguments that customers have an implied license to use LifeScan's meters with test strips other than
 16 LifeScan's test strips. The court held that the notice on the packaging for LifeScan's glucose meters
 17 "*preclud[es] a finding of implied license*," *id.* at *45 (emphasis added), and stated that the defendant
 18 "failed to convince the court that the [notice] placed on the [packaging for the] LifeScan One Touch
 19 meters ... is ineffectual, as a matter of law, to restrict the use of the meter." *Id.*³ The same
 20 conclusion applies here.

21 In addition, the fact that customers obtain LifeScan's glucose monitors for free or at
 22 heavily rebated prices makes it all the more unlikely that consumers would reasonably believe they
 23 have an implied license to use other company's test strips with LifeScan's monitors. These facts
 24 weigh heavily against a finding of implied license. *See Arizona Cartridge Remanufacturers Ass'n. v.*

25 ³ *See also LifeScan, Inc. v. Can-Am Care Corp.*, 859 F. Supp. 392, 395 (N.D. Cal. 1994) (denying
 26 defendants' motion for summary judgment on an implied license defense, and stating that "[the
 27 court] cannot determine that, as a matter of law, the license restriction [on the packaging of
 LifeScan's monitors] is ineffective" to negate an implied license to use the monitors with other
 company's test strips).

1 *Lexmark Int'l*, 421 F.3d 981, 988 (9th Cir. 2005) (restrictions on the use of a printer cartridge were
2 enforceable because customers "(1) have notice of the condition, (2) have a chance to reject the
3 [condition] on that basis and (3) receive consideration in the form of a reduced price in exchange for
4 the limits placed on reuse of the cartridge").

5 In light of all the relevant facts, Defendants cannot meet their burden of proving that
6 the circumstances of LifeScan's meter sales "plainly indicate that the grant of a license should be
7 inferred." *Met-Coil*, 803 F.2d at 686.

8 **2. Likelihood of Success for the '105 Patent: Validity/Enforceability**

9 Defendants have not asserted any substantial basis for challenging the validity or
10 enforceability of the '105 patent. *See Meyerhoff Decl.*, ¶ 49.

11 **B. Sales of the GenStrip Would Irreparably Harm LifeScan**

12 The second factor for a preliminary injunction is irreparable harm. This factor also
13 strongly favors a preliminary injunction.

14 As the Federal Circuit has held, "price erosion, loss of goodwill, damage to
15 reputation, and loss of business opportunities are all valid grounds for finding irreparable harm."
16 *Celsis in Vitro, Inc. v. Cellzdirect, Inc.*, 664 F.3d 922, 930 (Fed. Cir. 2012) (affirming the grant of
17 preliminary injunction); *see also Abbott Laboratories v. Sandoz, Inc.*, 544 F.3d 1341, 1362 (Fed. Cir.
18 2008) (affirming the grant of a preliminary injunction); *Robert Bosch LLC v. Pylon Mfg. Co.*, 659
19 F.3d 1142, 1151 (Fed. Cir. 2011) (finding irreparable harm and reversing the denial of a permanent
20 injunction). Sale of the GenStrip would cause all of these types of harm, and "the mere possibility of
21 future monetary damages does not defeat a motion for a preliminary injunction." *Celsis*, 664 F.3d at
22 930.

23 The GenStrip is designed to be a substitute for LifeScan's test strips, for use in
24 conjunction with LifeScan's OneTouch Ultra meters. As a result, the parties are in "direct
25 competition." *Bosch*, 659 F.3d at 1151. Sales of the GenStrip have a devastating effect on LifeScan
26 sales, and that effect would go beyond lost sales and profits. It could pose an existential challenge,
27 placing LifeScan's entire business in jeopardy. Defendants should not be permitted to use LifeScan's

1 patented technology without permission to compete with LifeScan and irreparably injure its
2 business.

3 **1. Sales of the GenStrip Would Decimate LifeScan's Business**

4 The GenStrip is designed and cleared for use with "for use with [LifeScan's]
5 OneTouch® Ultra®, Ultra® 2 and UltraMini® Meters purchased before July 2010." There are no
6 other uses. Menziuso Decl., ¶ 30. Defendants will promote the GenStrip as "comparable" to test
7 strips sold by the "platform manufacture," *i.e.*, LifeScan, but "priced significantly (50%) lower." *Id.*
8 ¶ 19.

9 Because the GenStrip is designed and approved for use with LifeScan's OneTouch
10 Ultra meters, as a substitute for LifeScan's OneTouch Ultra test strips, Shasta GenStrip sales would
11 have a crushing impact on LifeScan sales. And because Defendants' announced plan is to sell the
12 GenStrip at approximately half the price of LifeScan's OneTouch Ultra test strips, the losses to
13 LifeScan will vastly exceed the dollar amount of GenStrip sales.

14 The impact on LifeScan's business would be crushing. Statements on Defendant
15 DDC's website have indicated that Defendants expect to enjoy more than \$170 million in U.S. sales
16 of the GenStrip in its first full year on the market. *See* Menziuso Decl., ¶ 22. That estimate is not
17 unreasonable. *Id.* ¶ 23. Because GenStrip will be sold at half the price of LifeScan's, the impact on
18 LifeScan will be significantly greater and constitute a significant loss of its approximately \$1 billion
19 in annual sales revenues. DDC expects that sales of the GenStrip will sharply increase after the first
20 year. *Id.* ¶ 22.

21 The losses to LifeScan would run to hundreds of millions of dollars. And that is only
22 part of the story. GenStrip's low prices would force LifeScan to slash its price to compete. The
23 resulting loss of revenues and profits could decimate LifeScan's OneTouch Ultra business, placing
24 that entire business in severe jeopardy. This is an egregious example of irreparable harm. *See, e.g.,*,
25 *Washington Metropolitan Area Transit Comm'n v. Holiday Tours, Inc.*, 559 F.2d 841, 843 n.2 (D.C.
26 Cir. 1977); *Ajilon Prof'l Staffing, LLC v. Griffin*, No. CV-09-561, 2009 U.S. Dist. LEXIS 49328,
27 *10 (D. Ariz., May 29, 2009).

2. Loss of Market Share

"[L]oss in market share" can itself be irreparable harm. *Bosch*, 659 F.3d at 1151; *see also Purdue Pharma*, 237 F.3d at 1368 (Fed. Cir. 2001). That is particularly true here. LifeScan is the leader in the United States in the market for disposable blood glucose test strips. As the market leader, LifeScan enjoys a preeminent position, to which other companies aspire. Major competitors such as Abbott Diabetes Care, Roche and Bayer vie with LifeScan for leadership in this market. Menzuiso Decl., ¶ 7. Sales of the GenStrip, as a replacement for LifeScan's OneTouch Ultra test strips, would sharply reduce LifeScan's market share and jeopardize its position as the market leader. This would injure LifeScan in ways that could not be compensated through an award of money damages. *Bosch*, 659 F.3d at 1151; *Purdue Pharma*, 237 F.3d at 1368.

3. Questions About Defendants' Ability to Pay a Damage Award

"[Q]uestions about [Defendants'] ability to satisfy a judgment" present another recognized form of irreparable harm. *Bosch*, 659 F.3d 1154; *see also Buffalo Wings Factory, Inc. v. Mohd*, 1:07-CV-612 JCC 2008, U.S. Dist. LEXIS 86360, *12 (E.D. Va. Oct. 23, 2008) ("The harm caused by a defendant's inability to pay damages ... can be considered irreparable.").

There is every reason to believe that Defendants would not have sufficient resources to pay an award of lost profits on their infringing sales. Shasta's counsel has stated in open court that his client has "no product and no income stream whatsoever." D.E. 137 at 11. DDC stated in its publicly available S.E.C. filings for 2011, the last full year for which information is publicly available, that it had suffered a net loss of more than \$2 million. Menzuiso Decl., Ex. V at F-6. For the six months ending June 30, 2012, DDC reported to the S.E.C. that it was operating at a net loss and that it had just over \$7,000 in net cash. *Id.* Ex. W at 5. Defendant PharmaTech Solutions, Inc. is DDC's wholly-owned subsidiary. Information concerning the financial condition of the remaining Defendant, Conductive, is not publicly available.

There is no reason to expect that the Defendants – individually or collectively – would be able to satisfy an award of lost profits damages running to hundreds of millions of dollars

1 for the injury from their infringing sales. Their apparent inability to pay an award of LifeScan's lost
2 profits is, in itself, irreparable harm. *Bosch*, 659 F.3d 1154.

3 **4. Price Erosion**

4 Defendants have stated that they plan to sell the GenStrip at "significantly discounted
5 prices," *Celsis*, 664 F.3d at 930 – "approximately one-half" the price of OneTouch Ultra test strips.
6 Menziuso Decl., Exs. R, S. LifeScan would need to lower the price of OneTouch Ultra test strips to
7 compete with this lower priced alternative. Once the price of OneTouch Ultra strips is lowered, it
8 would be difficult or impossible to raise the price to earlier levels, even if the GenStrip is eventually
9 removed from the market. Attempting to do so would cause significant consumer anger and
10 resentment. As a result, sales of the GenStrip would cause a long-lasting drop in prices for
11 OneTouch Ultra strips. *Id.* ¶¶ 36-39. This "irreversible price erosion," by itself, constitutes
12 irreparable harm. *Bosch*, 659 F.3d at 1153-54; *see also id.* at 1155; *Sanofi-Synthelabo v. Apotex,*
13 *Inc.*, 470 F.3d 1368, 1382 (Fed. Cir. 2006).

14 **5. Injury to LifeScan's Goodwill**

15 Sales of a test strip that can be used in place of LifeScan's OneTouch Ultra test strips,
16 at a much lower price, would generate customer resentment against LifeScan, undermining the
17 goodwill that LifeScan has worked hard to develop. The resulting harm to LifeScan would be
18 difficult or impossible to quantify, and would occur even if LifeScan reduced the price of OneTouch
19 Ultra strips in response to the introduction of the Genstrip. *See* Menziuso Decl., ¶¶ 36-39.

20 **6. Loss of Revenues for R&D Efforts**

21 The Federal Circuit has recognized a reduction in revenues for research and
22 development activities as another type of irreparable harm. *Bio-Technology Gen. Corp. v.*
23 *Genentech, Inc.*, 80 F.3d 1553, 1566 (Fed. Cir. 1996). A decrease in LifeScan's revenues would
24 reduce the funds it has available for research and development and lead to inevitable layoffs. *See*
25 Menziuso Decl., ¶¶ 46-48. The resulting harm to LifeScan – and to the public in general – is
26 impossible to quantify. No one ever will know what potentially life-saving products could have
27 been developed if LifeScan had additional funds available to invest in research and development.

7. Injury to Reputation

LifeScan's OneTouch Ultra test strips have been on the market for more than eleven years and have a proven track record when used with LifeScan's OneTouch Ultra meters. The same cannot be said for the GenStrip. If there are manufacturing or design defects or problems with GenStrip test strips, then customers would be likely to blame LifeScan and its OneTouch meters for any resulting problems, even if the cause were Defendants' GenStrip product. This would injure LifeScan's reputation and would further harm the goodwill it has worked hard to develop. *See Menziuso Decl.*, ¶ 28.

These concerns are heightened by the unusual conditions of FDA clearance for the GenStrip. The GenStrip is only approved for calibration codes 4, 10 and 13, and for LifeScan meters sold before July 2010. *Id.* Ex. Q at 4. Users of LifeScan's OneTouch Ultra meters are accustomed to meters that are pre-set to a single calibration code (code 25) and are accustomed to not entering a one of several calibration codes before using a test strip. If GenStrip users do not re-set the calibration code on the meter, or do not correctly set it to a calibration code that matches the code for GenStrip, then users would unfairly attribute any resulting problems to LifeScan. *Id.* ¶ 33.

8. Loss of the Right to Exclude

Sales of the GenStrip also would deprive LifeScan of the principal value of the patents, *i.e.*, the right to exclude infringers. "Absent a preliminary injunction, [LifeScan] would lose the value of [the] patent" *Celsis*, 664 F.3d at 931; "[T]he principal value of a patent is its statutory right to exclude" *Black & Decker, Inc. v. Robert Bosch Tool Corp.*, 2006 WL 3446144, *3 (N.D. Ill. Nov. 29, 2006), quoting *Reebok Int'l, Ltd. v. J. Baker, Inc.*, 32 F.3d 1552, 1557 (Fed. Cir. 1994); *see also id.* (quoting *Reebok*, 32 F.3d at 1557) (the "nature of the patent grant weighs against holding that monetary damages will always suffice to make the patentee whole."); *Martek Biosciences Corp. v. Nutrinova, Inc.*, 520 F. Supp. 2d 537, 558-59 (D. Del. 2007) (the statutory right to exclude is a "benefit associated with patent rights that cannot be quantified in money damages.").

Where, as here, the patentee and the infringer directly compete then "[m]onetary damages generally are not an adequate remedy against future infringement because the central value of holding a patent is the right to exclude others from using the patented product." *Smith & Nephew, Inc. v. Synthes (U.S.A.)*, 466 F. Supp. 2d 978, 984 (W.D. Tenn. 2006). The parties to this case "are head-to-head competitors, and [LifeScan] has a right, granted by Congress, not to assist its rival with the use of proprietary technology." *Novozymes A/S v. Genencor Int'l, Inc.*, 474 F. Supp. 2d 592, 613 (D. Del. 2007).

9. Injury from False Advertising and Promotion

LifeScan has filed a separate complaint and motion for a preliminary injunction alleging that Defendants, by their packaging and promotion of the GenStrip, have confused consumers and infringed LifeScan's trademarks and trade dress. Of course, Defendants' decision to market the GenStrip in unlawful ways is independent of the patent law violations alleged here, but it is also true that the irreparable injury alleged in that case would not have occurred if Defendants had respected LifeScan's patent rights and foregone its effort to market the GenStrip.

C. The Balance of the Equities Favors a Preliminary Injunction

The third factor is the balance of equities. This factor weighs heavily in favor of a preliminary injunction. Absent an injunction, Defendants would be using LifeScan's patented technology without its permission to compete with LifeScan and irreparably injure its business in many ways. *See Menziuso Decl.*, ¶¶ 3,61. All of the equities in this situation favor LifeScan.

Defendants were aware of the patents-in-suit at all relevant times, but chose to proceed nonetheless in developing their infringing product. Even if an injunction would harm Defendants, "[o]ne who elects to build a business on a product found to infringe cannot be heard to complain if an injunction against continuing infringement destroys the business so elected." *Bosch*, 659 F.3d at 1156 (quoting *Windsurfing Int'l, Inc. v. AMF, Inc.*, 782 F.2d 995, 1003, n.12 (Fed. Cir. 1986)); *see also Sanofi-Synthelabo*, 470 F.3d at 1382 (balance of hardships favors the patentee where the infringer has taken a "calculated risk" by launching its product before a final judgment). This conclusion applies with particular force where, as here, the parties are direct competitors and

denial of an injunction would "requir[e] [the patentee] to compete against its own patented invention, with the resultant harms, ... plac[ing] a substantial burden on [the patentee]." *Bosch*, 659 F.3d at 1156. That would put LifeScan in a position antithetical to the patent grant, of "assist[ing] its rival with the use of proprietary technology," *Novozymes*, 474 F. Supp. 2d at 613. In these circumstances, "there can be little doubt that the balance of hardships favors [LifeScan]." *Amgen Inc., v. F. Hoffmann-LaRoche Ltd.*, No. 05-12237, 2008 WL 4452454 at*48 (D. Mass. Oct. 2, 2008)

The analysis is not altered by the importance that the infringing product may have to Defendants' businesses or by the fact that Defendants are smaller than LifeScan and its parent Johnson & Johnson. "A party cannot escape an injunction simply because it is smaller than the patentee or because its primary product is an infringing one." *Bosch*, 659 F.3d at 1156.

D. The Public Interest Favors a Preliminary Injunction

The fourth and final factor – the public interest – also weighs heavily in favor of an injunction. As the Supreme Court has recognized, "[t]he patent laws promote ... progress by offering a right of exclusion for a limited period as an incentive to inventors to risk the often enormous costs in terms of time, research and development" needed to create a new product and bring it to the market. *Kewanee Oil Co. v. Bicron Corp.*, 416 U.S. 470, 480 (1974). Similarly, the Federal Circuit has "long acknowledged the importance of the patent system in encouraging innovation." *Sanofi-Synthelabo*, 470 F.3d at 1383. Indeed, the "encouragement of investment-based risk is the fundamental purpose of the patent grant, and is based directly on the right to exclude." *Id.* (citation omitted).

These incentives are particularly important in the field of medical products, both drugs and devices. *See id.* (recognizing that enjoining patent infringement serves the important role of "provid[ing] incentive to the innovative drug companies to continue costly development efforts."). *Amgen*, 2008 WL 4452454, is instructive (*id.*, *62):

Were courts to refuse injunctions on the [grounds that costs might be reduced and some patients might benefit], then pharmaceutical patents would be worth far less than they are today because they would no longer include a right to exclude infringers from the market. The diminishing returns would disincentivize research and

development for pathbreaking drugs by lowering the expected value of discovery. By contrast, granting injunctions encourages companies to devote their energies toward developing drugs that will satisfy unmet medical needs. Were it possible to obtain market entry by making incremental improvements to existing drugs, it is doubtful that companies designed to generate discoveries could exist.

The Federal Circuit has endorsed this reasoning. In *Abbott Laboratories v. Sandoz, Inc.*, 544 F.3d 1341 (Fed. Cir. 2008), the district court granted a preliminary injunction against the sale of an infringing drug, stating (*id.* at 1362):

The Court recognizes the public interest in competition in the pharmaceutical market. It also recognizes, however, the public interest in creating beneficial and useful products and the cost involved in that process. To the extent that this Court has found a substantial likelihood that the '718 patent is valid and enforceable, there can be no serious argument that public interest is not best served by enforcing it.

In affirming the grant of a preliminary injunction, the Federal Circuit quoted the above reasoning with approval and gave the district court credit for "appreciat[ing] that the public interest includes consideration of whether ... the incentive for discovery and development of new products is adversely affected." *Id.* The Federal Circuit stated:

The statutory period of exclusivity reflects the congressional balance of interests, and warrants weight in considering the public interest. In *Sanofi-Synthelabo [v. Apotex, Inc.]*, 470 F.3d [1368,] at 1383 [Fed. Cir. 2006], this court referred to the significant "public interest in encouraging investment in drug development and protecting the exclusionary rights conveyed in valid pharmaceutical patents." *Id.* at 1362-63

Courts have recognized the strong public interest in enjoining the sale of infringing drugs or medical devices where, as here, the infringing product competes with a product sold by the patentee. *See, e.g., Celsis*, 664 F.3d 922 (affirming a preliminary injunction against a device for preparing multi-cryopreserved hepatocytes, a type of liver cell); *Abbott Laboratories*, 544 F.3d 1341 (affirming a preliminary injunction against a pharmaceutical product); *Sanofi-Synthelabo*, 470 F.3d 1368 (affirming a preliminary injunction against an infringing platelet aggregation inhibiting agent); *Amgen*, 2008 WL 4452454 (granting a permanent injunction against a recombinant product used for treatment of anemia); *Smith & Nephew*, 466 F. Supp. 2d at 985 ("As a general matter, the public

maintains an interest in protecting the rights of patent holders, and injunctions serve that interest.")
(granting a permanent injunction against sale of a device to treat femoral fractures).

The fact that Defendants plan to sell the Shasta GenStrip at a lower price than LifeScan's test strips does not alter the analysis of the public interest factor. "Selling a lower priced product does not justify infringing a patent," *Pfizer, Inc. v. Teva Pharm., USA, Inc.*, 429 F.3d 1369, 1382 (Fed. Cir. 2005), quoting *Payless Shoesource, Inc. v. Reebok Int'l Ltd.*, 998 F.2d 985, 991 (Fed. Cir. 1993), and price considerations do not trump the exclusionary rights conveyed by medical device patents. *Id.* Defendants took "a calculated risk that [they] might infringe" a valid patent when they decided to develop the Shasta GenStrip with knowledge of LifeScan's patents. *Smith Int'l, Inc. v. Hughes Tool Co.*, 718 F.2d 1573, 1581 (Fed. Cir 1983). Having taken that risk, Defendants should "not now be heard to say that public policy is in [their] favor." *Id.*

CONCLUSION

For the reasons set forth above, this Court should enter a preliminary injunction barring Defendants from selling or offering to the sell the infringing Shasta GenStrip.

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